

REMARKS/ARGUMENT

Claims 1-4, 7-8, 10-14, and 16-20 are pending in the application.

Claim 1 has been amended so as to delete the specific CETP inhibitor; support is in the originally filed claims. Claim 1 has also been amended to specify that the substrate is selected from the group consisting of inorganic oxides, zeolites, clays, and activated carbons; support is found in paragraph [1088] of published application US 2004/0132771.

Claim 3 has been amended to remove the term "further," thereby specifying that the concentration-enhancing polymer is present in the solid amorphous adsorbate.

New claims 16-20 have been added. Claims 16-18 recite specific substrates; support is found in paragraph [1088] of the published application. Claim 19, which is dependent from claim 11, specifies that the dissolution-enhancing agent is selected from the group consisting of polyvinylpyrrolidone and poloxamers; support is found in paragraph [1137] of the published application. Independent claim 20 combines amended claim 1, claim 11, claim 17, and claim 19; support for this claim is as noted above.

Accordingly, no new matter has been added by this Amendment.

Turning to the outstanding rejections, claim 3, which is dependent from claim 2, is objected to under 37 CFR 1.75(c) for failing to further limit the subject matter of claim 2. Amended claim 3 now specifies that the solid amorphous adsorbate comprises the concentration-enhancing polymer recited in claim 2, which further limits the subject matter of claim 2, so withdrawal of this objection is requested.

Claims 1-4, 7-8, and 10-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sikorski WO 00/38722 in view of Gurtler U.S. 5,773,021, Mulligan U.S. 5,128,142, and Rower US 2003/0099708, the Examiner reasoning that Sikorski teaches combinations of CETP

inhibitors and HMG-CoA reductase inhibitors, that Gurtler teaches a polymeric matrix material of cellulose acetate trimellitate, that Mulligan teaches an active adsorbed onto a cross-linked polymer, that Rower teaches increasing the bioavailability of an API by altering its structure to be amorphous, and that it would have been obvious to modify the Sikorski composition by adsorbing a drug composition onto a crosslinked polymer as taught by Gurtler, to use PVP as taught by Mulligan, and to have an active such as a CETP in amorphous form, as taught by Rower. This rejection is respectfully traversed for the following reasons.

Applicants concede that Sikorski teaches combinations of CETP inhibitors and HMG-CoA reductase inhibitors. However, Sikorski does not teach the use of a solid adsorbate to increase the bioavailability of the CETP inhibitor, let alone any of the substrates now specified in amended claim 1. And none of the three secondary references supply these deficiencies.

Gurtler discloses a "bioadhesive ophthalmic insert...for the prolonged and controlled release of a medicinal substance." Gurtler, abstract and claim 1. Gurtler's insert is placed in or near the eye; see Example 1 where the ophthalmic insert is placed in the rear part of the conjunctival sac of rabbits. There is no suggestion whatsoever in Gurtler as to improving the bioavailability of the medicinal substance, no mention of CETP inhibitors, and no reference to the use of the substrates now specified in amended claim 1.

Mulligan discloses to a controlled-release formulation comprising an active and inactives adsorbed onto a cross-linked polymer substrate. There is no disclosure or suggestion of the substrates now specified in amended claim 1, and no mention of CETP inhibitors.

The Examiner cites Rowerr to demonstrate that the amorphous form of drug increases its bioavailability, which is conceded. However, Rower does not disclose or suggest formation of a solid adsorbate to increase bioavailability, let alone any of the substrates now specified in amended claim 1.

In summary, the prior art of record does not disclose or suggest improving bioavailability by forming a solid amorphous adsorbate on the substrates specified in amended claim 1. Accordingly, withdrawal of the obviousness rejection is respectfully requested.

New independent claim 20 is novel and not rendered obvious by the prior art. None of the four references, either alone or in combination, disclose or suggest a composition comprising a solid adsorbate comprising a CETP inhibitor and a polyvinylpyrrolidone or poloxamer dissolution-enhancing agent adsorbed onto the substrates recited in claim 20, combined with an HMG-CoA reductase inhibitor.

Claims 1-4, 10 and 13 stand rejected on the grounds of nonstatutory obviousness-type double patenting over copending Application No. 10/173,987 in view of Sikorski. Upon notice of allowable subject matter, applicants will submit a terminal disclaimer, thereby removing this rejection.

Claims 1-4, 7-8, 10 and 14 also stand rejected on the grounds of nonstatutory obviousness-type double patenting over copending Application No. 10/739,750 in view of Gurtler and Mulligan. The shortcomings of the disclosures of Gurtler and Mulligan are discussed above. It is submitted that the amended claims overcome this rejection, and so withdrawal of the rejection is in order.

Claims 1-4, 7-8, 10 and 13 also stand rejected on the grounds of nonstatutory obviousness-type double patenting over copending Application No. 11/566,408 in view of Sikorski. Upon notice of allowable subject matter, applicants will submit a terminal disclaimer, thereby removing this rejection.

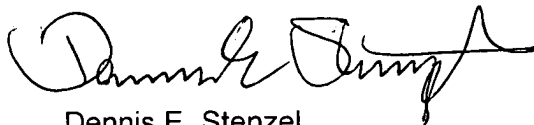
Finally, claims 1, 7-8 and 13 stand rejected on the grounds of nonstatutory obviousness-type double patenting over copending Application No. 11/759,743 [sic] in view of Sikorski. In a telephone conference, the Examiner corrected the Serial No. to 11/795,743. But Application No. 11/795,743 was filed through the PCT, on January 30, 2006, with a priority date of February

Application No. 10/678,145
AMENDMENT - Dated December 23 2008

8, 2005. Since the filing date of the instant application is October 6, 2003, Application No. 11/795,743 is not available under §102 as prior art.

Early and favorable reconsideration is respectfully solicited.

Respectfully submitted,

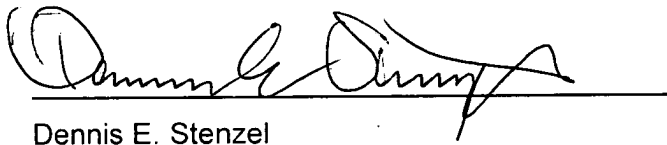


Dennis E. Stenzel
Reg. No. 28,763
Tel No.: (503) 227-5631

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Dennis E. Stenzel